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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/781,721	02/12/2001	William Richard Dubrul	ARTM 1008-5 US	8945
34263	7590	10/05/2004	EXAMINER	
O'MELVENY & MEYERS 114 PACIFICA, SUITE 100 IRVINE, CA 92618			WILLIAMS, CATHERINE SERKE	
			ART UNIT	PAPER NUMBER
			3763	

DATE MAILED: 10/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/781,721

Applicant(s)

DUBRUL ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-30, 32 and 39-55 is/are pending in the application.
4a) Of the above claim(s) 39-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-30 and 32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 26-27, 29 and 32 are rejected under 35 U.S.C. 102(e) as being anticipated by Klein (US Pat# 5,810,767). Klein discloses a method and apparatus for intraluminal drug delivery that includes positioning a porous tubular braid with a contact dispensable agent at a target site within a passageway of a body; expanding the braid against the body tissue, and dispensing the agent from the braid into the body tissue. See 6:19-39. The braid is expanded by a radially-expandable element (13). While the reference does not specifically disclose contracting and removing the radially-expansive element and the tubular braid from the body, it is considered inherent since the element and the braid are structurally attached and the device is designed to be removed from the body. The device further includes a balloon (B see figure 12). The dispensing step is carries out as a result of the expanding step. See 11:31-12:25. The porous tubular braid is not bioabsorbable and may constructed from nylon. See 7:50.

Claims 26 and 28-30 are rejected under 35 U.S.C. 102(e) as being anticipated by Brown, III et al (US Pat# 6,219,577). Brown discloses a iontophoresis catheter for local drug delivery that includes positioning a porous tubular braid with a contact dispensable agent (see 9:17-22) at

Art Unit: 3763

a target site within a passageway of a body; expanding the braid against the body tissue, and dispensing the agent from the braid into the body tissue. See 10:35-59. The braid is expanded by a radially-expandable element (24) within the braid. While the reference does not specifically disclose contracting and removing the radially-expandable element and the tubular braid from the body, it is considered inherent since the element and the braid are structurally attached and the device is designed to be removed from the body. The braid include absorbent polyester monofilaments. See 9:4-9. The dispensing step is carried out as a result of the expanding step using iontophoresis. See 9:4-30.

Response to Arguments

Applicant's arguments with respect to the claims have been considered and are not persuasive.

Applicant argues that the braid of Klein would be spaced radially inwardly from the target tissue and would not comprise a contact-dispensable agent. However, the drug infusion tubes are part of the tubular braid. The tubular braid makes intimate contact with the vessel wall via the tubes and the drug is released when the tubes make contact with the vessel wall.

Applicant argues that Brown does not disclose a true braid. However, Brown discloses "The sleeve 20 may also comprise polyester monofilaments 28 (preferably of the same thickness as the wire electrodes) intercalated between the electrodes 24 during the braiding process". Additionally, it is noted that the features upon which applicant relies (i.e., true tubular braid) are not recited in the rejected claim(s). Although the claims are interpreted in light of the

Art Unit: 3763

specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846 (after Nov. 2nd 571-272-4970). The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 703-308-2698. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams (CSW).
October 3, 2004



LOAN H. THANH
PRIMARY EXAMINER